

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In Re Application of: Scott A. Waldman et al.

Serial No.: 10/656,895

Group Art Unit: 1643

Filing Date: September 5, 2003

Examiner: Rawlings, Stephen L.

For: **Compositions That Specifically Bind to Colorectal Cancer Cells and Methods of Using the Same**

Express Mail Label No. EV 882727390 US  
Date of Deposit: October 13, 2006

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08B, formerly known as PTO Form 1449, submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Supplemental Information Disclosure Statement is being filed:**

- within three months of the filing date of the patent application.
- within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- before the mailing date of a first Office Action on the merits.
- before the mailing date of a first Office Action on the merits after the filing of a Request for Continued Examination under § 1.114.

- after the mailing date of a first Office Action on the merits or after the filing of a Request for Continued Examination under § 1.114, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
  - the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);

or
  - the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
  - No fee is owed by the applicant(s).
- In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with the  first or  second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- after the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), and the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p).
- Copies of Citation Nos. 9-27 listed on the attached PTO Forms SB/08a and SB/08b, formerly known as PTO Form 1449, are enclosed. Please note in view of the filing date of the subject application, the U.S. Patent Documents identified as Citation Nos. 3-8 are not enclosed. EXCEPT THAT:
  - In view of the voluminous nature of references, and the likelihood that these reference are available to the Examiner, copies are not enclosed herewith.
  - In accordance with 37 C.F.R. § 1.98(d), copies of references identified as Citation Nos. 28-33 listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) 09/649,697 for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 C.F.R. § 1.704(d)**

The undersigned attorney hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and the communication was not received by any individual designated in §1.56(c) more than 30 days prior to the filing of the Information Disclosure Statement.

**Fees**

No Fee is owed by the applicant(s).

The Supplemental Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

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Attached is a check in the amount of \$\_\_\_\_\_ . This form is submitted in duplicate.

Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.

Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.

No fee or Statement is required under 37 C.F.R. § 1.97(b).

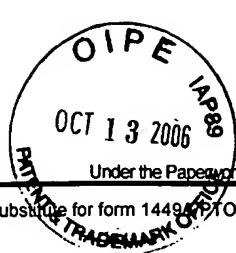
Respectfully submitted,



**Mark DeLuca**  
Registration No. 33,229

Dated: October 13, 2006

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Substitute for form 14494 PTO <b>TRADEMARK</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/656,895
		Filing Date	September 5, 2003
		First Named Inventor	Scott A. Waldman
		Art Unit	1643
		Examiner Name	Stephen L. Rawlings
Sheet	1	of	3
		Attorney Docket Number	
		TJU0007-103	

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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<sup>4</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO				<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/656,895
(Use as many sheets as necessary)				Filing Date	September 5, 2003
				First Named Inventor	Scott A. Waldman
				Art Unit	1643
				Examiner Name	Stephen L. Rawlings
Sheet	2	of	3	Attorney Docket Number	TJU0007-103

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	10	Carrithers, et al., "Escherichia Coli Heat-Stable Toxin Receptors in Human Colonic Tumors", <i>Gastroenterology</i> , 1994, 107, 1653-1661		
	11	Carrithers, et Al., "Guanylyl Cyclase C Is A Selective Marker For Metastatic Colorectal Tumors In Human Extraintestinal Tissues", <i>Proc. Natl. Acad. Sci USA</i> , 1996, 93, 14827-14832		
	12	Ohyama, et al., "Cloning and Characterization of Two Forms of C-Type Natriuretic Peptide Receptor in Rat Brain", <i>Biochem. &amp; Biophys. Res. Comm.</i> , 1992, 183, 743-749		
	13	Singh, et al., "Isolation and Expression of a Guanylate Cyclase-Coupled Heat Stable Enterotoxin Receptor cDNA from a Human Colonic Cell Line", <i>Biochem. &amp; Biophys. Res. Commun.</i> , 1991, 179, 1455-1463		
	14	Tallerico-Melniky, et al., "A Novel Guanylyl Cyclase-A Isoform: Rat GC-A1 Identification and mRNA Localization to Renal Papilla and Adrenal", <i>Biochem. &amp; Biophys. Res. Commun.</i> , 1995, 209, 930-935		
	15	Bostick PJ, et al., "Limitations Of Specific Reverse-Transcriptase Polymerase Chain Reaction Markers In The Detection Of Metastases In The Lymph Nodes And Blood Of Breast Cancer Patients", <i>J. Clin. Oncol.</i> 1998,16(8): 2632-40		
	16	Crutchfield GC, "The Future Of DNA Diagnostics", <i>Disease Markers</i> , 1999, 15, 108-11		
	17	Sidransky D, "Nucleic Acid-Based Methods For The Detection Of Cancer " <i>Science</i> , 1997, 278, 1054-9		
	18	Cagir B, et al., "Guanylyl Cyclase C Messenger RNA Is A Biomarker For Recurrent Stage II Colorectal Cancer " <i>Annals Int Med.</i> , 1999, 131(11), 805-12		
	19	Bustin SA, et al., "Detection Of Cytokeratins 19/20 And Guanylyl Cyclase C In Peripheral Blood Of Colorectal Cancer Patients", <i>Br J Cancer</i> , 1999, 79(11-12), 1813-20		
	20	Castells A, et al., "Detection of Colonic Cells In Peripheral Blood Of Colorectal Cancer Patients By Means Of Reverse Transcriptase And Polymerase Chain Reaction ", <i>Br J Cancer</i> , 1998, 78(10), 1368-72		
	21	Park J, et al., "Ectopic Expression Of Guanylyl Cyclase C In Adenocarcinomas Of The Esophagus And Stomach", <i>Cancer Epidemiol Biomarkers Prev.</i> , 2002, 11, 739-44		
	22	Fava TA, et al., "Ectopic Expression Of Guanylyl Cyclase C In CD34+ Progenitor Cells In Peripheral Blood", <i>Cancer Epidemiol Biomarkers Prev.</i> , 2001, 19(19), 3951-9		
	23	Vleminckx FA, et al., "Investigations For A Multi-Marker RT-PCR To Improve Sensitivity Of Disseminated Tumor Cell Detection", <i>Anticancer Res.</i> 2003, 23(1A), 179-86		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO				<b>Complete if Known</b>	
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				Art Unit	1643
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Sheet	3	of	3	Attorney Docket Number	TJU0007-103

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	24	Michalevicz R, et al., "Characterization Of Lympho-Myeloid-Erythroid-Megakaryocytic Stem Cells In Peripheral Blood Of Hairy Cell Leukemia Patients ", Leuk. Res., 1989, 13(10), 915-20		
	25	Silvestri F., et al., "The CD34 Hemopoietic Progenitor Cell Associated Antigen: Biology And Clinical Applications", Haematologica, 1992, 77(3), 265-73		
	26	Ward AM, "Tumour Markers", Develop Oncol., 1985, 21, 91-106		
	27	Tockman MS, et al., "Considerations In Bringing A Cancer Biomarker To Clinical Application", Cancer Res., 1992, 52, 2711s-2718s		
	28	Boehringer Mannheim Biochemicals, 1994 Catalog (No. 1034 731/1006 924), page 93		
	29	Houdebine LM, "Production Of Pharmaceutical Proteins From Transgenic Animals ", J Biotechnol., 1994, 34(3), 269-87		
	30	Verma IM, et al., "Gene Therapy -- Promises, Problems And Prospects " Nature, 1997, 389(6648), 239-42		
	31	Patterson AP, Memorandum (January 14, 2003), page 3		
	32	Pandha HS, et al., "Oncological Applications Of Gene Therapy", Cur Gene Ther., 2002, 2, 111-33		
	33	Amalfitano A, et al, "Separating Fact From Fiction: Assessing The Potential Of Modified Adenovirus Vectors For Use In Human Gene Therapy ", Cur Gene Ther. 2002, 2, 111-33		

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/656,895
Filing Date	September 5, 2003
First Named Inventor	Scott A. Waldman
Art Unit	1643
Examiner Name	Rawlings, Stephen L.
Attorney Docket Number	TJU0007-103

### ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form SB08a/ Form SB08b (3pgs. total); 31 References Cited, (19) References Enclosed.
<b>Remarks</b> EXPRESS MAIL LABEL NO: EV 882727390 US DATE OF DEPOSIT: October 13, 2006 <b>EV882727390US</b>		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	Cozen O'Connor		
Signature			
Printed Name	Mark DeLuca		
Date	October 13, 2006	Reg. No.	33,229

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